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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,434

04/16/2004

Joseph Levy

LEVY=18A

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,434	Applicant(s) LEVY ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks filed 04/14/10 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment to the claims and/or persuasive remarks: (1) The 35 U.S.C. §112, first paragraph rejection of claims 19 and 23-26 (based on new matter) has been withdrawn; and (2) The 35 U.S.C. §103(a) rejection over Jackson et al. (USPN 5,807,586) of claims 19 and 23 has been withdrawn.

Claims 19 and 27 are pending in this action. Claim 19 has been amended. New claim 27 has been added. Claims 1-18 and 20-26 have been cancelled. Claims 19 and 27 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson *et al.* (hereafter “Jackson”) (U.S. Pat. No. 5,807,586) in view of Schlipalius (U.S. Pat. No. 6,132,790).

Jackson (‘586) teaches a dietary supplement composition and method for supplementing the dietary needs of a women comprising once daily administration of a composition comprising a physiologically effective amount of phytoestrogens in combination with mixed carotenoids having non-provitamin A activity, such as lycopene and lutein (see reference column 1, lines 4-10); (col. 4, line 39 – col. 5, line 14); (col. 6, line 63 – col. 7, line 25) and Table 1 at column 10. The teaching of “lutein” meets the Markush grouping of claim 23.

The dietary supplements are formulated to *reduce the risk factors of disease*, such as iron deficiency anemia, high cholesterol and CHD, osteoporosis and some cancers during the various life stages of a woman (col. 7, lines 25-35). The intake of the carotenoid, lycopene, has also been inversely associated with the risk of cervical cancer (col. 7, lines 4-9). Jackson also teaches that in general, the risk of cancer increases with age. Thus, the antioxidants and phytoestrogens appear to have a role in the prevention of some cancers, particularly breast cancer (col. 1, lines 40-45). At column 9, Jackson also states that the amount of phytoestrogens contributes to the reduction of some forms of cancer and is therefore increased in the composition for the second life stage (col. 9, lines 55-59). Thus, these teachings read on the “method for reducing the risk for developing cancer” as presently claimed by Applicant.

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Regarding the claim limitation of claim 19, that the dosage form is one "having as active ingredients only at least one phytoestrogen and at least one carotenoid", it is noted that Jackson includes some additional elements in their composition, besides from the phytoestrogens and carotenoids, such as vitamins and minerals. However, a review of the instant specification demonstrates that Applicant's themselves permit the inclusion of additional active ingredients, in addition to the phytoestrogens and carotenoids, such as the additional hormones as shown on p. 12, lower half of 2nd paragraph. Thus, it cannot be seen as to how the additional vitamins and minerals of Jackson would be adversary to the instant formulation, since Applicants explicitly permit the inclusion of additional actives in their formulation. No closed-ended (i.e., "consisting of") claim language has been presented which would exclude the additional vitamins and minerals of Jackson. Consequently, Jackson remains relevant for its teachings.

The dietary supplements may be formulated as a tablet, capsule, powder, gel or liquid, or dietary bar and are preferably formulated for once daily administration (col. 3, lines 22-26). The phytoestrogens may be administered at levels of less than 25 mg per day (col. 5, lines 6-14).

With regards to the amount of carotenoid claimed, as in claim 27, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Moreover, it is deemed to one of ordinary skill in the art to determine suitable ranges, percentages or ratios through routine or manipulative experimentation, to obtain the best possible results, as these are variable parameters attainable

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within the art. Furthermore, no unexpected or superior results have been observed in the instant amounts of carotenoid claimed (of about 2 mg or amount sufficient to cause effective serum concentration of the carotenoid of up to about 1.5 microM). The prior art clearly teaches a formulation having the same ingredients (phytoestrogens/carotenoids), whereby the formulation is effective to reduce the risk factors for various diseases, including some cancers. Jackson teaches the concept of providing a dietary supplement composition having a combination of phytoestrogens with mixed carotenoids to combat diseases such as cancer. Hence, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Jackson.

Jackson does not teach a combination of carotenoids comprising lycopene and at least one of phytoene and phytofluene as in present claim 19.

Schlupalius ('790) teaches a carotenoid composition comprising carotenoids that include lycopene, phytoene, phytofluene and mixtures thereof (see col. 3, lines 10-19) and claim 10. The carotenoid composition is derived from natural resources to result in a natural carotenoid composition (col. 1, lines 10-13). Lutein is also disclosed amongst suitable carotenoids (col. 3, line 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a mixture of carotenoids, such as a mixture of lycopene, phytoene and phytofluene as taught by Schlupalius within the formulations of Jackson. One would do so with a reasonable expectation of success because Schlupalius teaches a formulation mixture of carotenoids (*i.e.*, lycopene, phytoene and phytofluene), which, as evidenced by Jackson, are known to provide beneficial antioxidant activity and reduce the risk factors of various diseases,

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such as cancers, based on the use of carotenoids. The expected result would be an effective method for reducing the risk potential for acquiring diseases (i.e., cancers).

* * * * *

Response to Arguments

Applicant's arguments filed 28 July 2009 have been fully considered but were not found to be persuasive.

▪ **Claim Rejections - 35 USC § 112:**

Applicant's arguments regarding the 35 U.S.C. §112, first paragraph rejection of claims 19 and 23-26 (based on new matter) (found on pages 4-11 of the Response dated 04/14/10) have been considered and were found to be persuasive. Accordingly, this rejection has been withdrawn.

▪ **35 U.S.C. §103(a) rejection over Jackson et al. (US '586) alone:**

Applicant argued, "Applicants need not address this rejection at the present time in view of the fact that claim 19 has been amended to incorporate the dependent parts alternatively from claims 24-26 and claims 24-26 have not been rejected as obvious from Jackson. Applicants understand that this rejection is not intended by the PTO to apply to claim 19 in its present form."

Applicant's arguments have been considered and were found to be persuasive, based on the amendment to claim 19. Accordingly, the 35 U.S.C. §103(a) rejection over Jackson alone has been withdrawn.

▪ **35 U.S.C. §103(a) rejection over Jackson et al. (US '586) in view of Schlipalius (US '790):**

Applicant argued, “Jackson teaches administration of phytoestrogen in order to reduce the risk for developing cancer caused by other agents present in the body of the subject being treated. This is the complete opposite of the present invention, in which phytoestrogens are administered as HRT agents which are actually expected to increase the risk for developing cancer. The method of the present invention comprises the administration of carotenoids in order to prevent or reduce the proliferative effect caused by the simultaneous administration of phytoestrogen.”

Applicant's arguments have been considered but were not found to be persuasive. Applicant is arguing an inherent property of the phytoestrogens, namely, that they have the ability “to increase the risk for developing cancer”. The argument of the particular property or result that is imparted by the phytoestrogens is not sufficient to overcome the obviousness of the rejections since the prior art of Jackson explicitly teaches methods (for supplementing the dietary needs of women) comprising once daily administration of a composition comprising a physiologically effective amount of phytoestrogens in combination with mixed carotenoids having non-provitamin A activity, such as lycopene and lutein (see column 1, lines 4-10); (col. 4, line 39 – col. 5, line 14); (col. 6, line 63 – col. 7, line 25) and Table 1 at column 10. Jackson thus teaches co-administration of phytoestrogens with carotenoids, the same process step employed by Applicant. Hence, the argument that in Jackson, the “administration of phytoestrogen is to reduce the risk for developing cancer caused by other agents” was not persuasive since the art is

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well aware of co-administration of phytoestrogens with carotenoids to yield beneficial results. The fact that the phytoestrogens of Jackson can have alternative uses does not deter one of ordinary skill in the art from utilizing Jackson's compositions which clearly comprise phytoestrogens in combination with mixed carotenoids. Thus, Applicant's arguments were not persuasive.

Applicant argued, "Schlipalius provides no teaching whatsoever for the anti-proliferative effect of the carotenoids or for specific synergistic carotenoid combinations."

The Examiner did not find this argument convincing. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the secondary reference of Schlipalius amply resolves the deficiency of Jackson and was relied upon for the teaching that it is well known in the art to employ a combination of or a mixture of carotenoids. Schlipalius vividly teaches a carotenoid composition comprising the same carotenoids claimed by Applicant - namely, lycopene, phytoene and phytofluene and mixtures thereof (see col. 3, lines 10-19 of Schlipalius). Hence, the composition of Schlipalius would also provide for beneficial results, based on inclusion of the same components, absent a showing of evidence to the contrary. Moreover, it is not incumbent that the secondary reference of Schlipalius recognize the anti-proliferative effect of the carotenoids but merely that it suggests and teaches the various

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combinations thereof (i.e., lycopene with phytoene or phytofluene) is sufficient to render the instant claims *prima facie* obvious. Furthermore, while it is noted that Schlipalius does not discuss the potential benefits of the carotenoids, note in particular, that the primary reference of Jackson initially teaches and evidences that the inclusion of non-provitamin A activity carotenoids, such as lycopene, are known to reduce the risk of certain cancers, such as cervical cancer (col. 7, lines 4-9). Thus, there is a direct correlation between intake of carotenoids and its' effect on diseases. One of ordinary skill in the art reading the teachings of Jackson would conclude that carotenoids are effective in reducing the potential risks of diseases, particularly cancers. Thus, one would also presume that the composition of Schlipalius, which comprises a mixture of carotenoids (having non-provitamin A activity) would also be exceptionally beneficial for reducing the risk factors for disease (i.e. cancers), based on Jackson who demonstrates the positive effects exhibited by carotenoids on diseases.

Applicant argued, "The disclosure of Schlipalius does not make it obvious to select from the listing of carotenoids disclosed, the mixture of lycopene together with phytoene and/or phytofluene".

This argument was not persuasive. The reference of Schlipalius discloses carotenoids that include lycopene, phytoene, phytofluene and mixtures thereof (see col. 3, lines 10-19 and claim 10). Hence, one of ordinary skill in the art would be reasonably motivated to employ any combination of carotenoids from those disclosed by Schlipalius, including the combination being presently claimed, namely, the combination of lycopene with either phytoene and/or phytofluene. The reference vividly suggests that mixtures of carotenoids can be used and thus one would be

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able to vary the particular combination of carotenoids based on the intended outcome or desired result. This rejection has been maintained herein.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

July 2, 2010

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